

[0524]

[0525] CLAIMS

1. A foam comprising a liquid phase and a gas phase wherein
5 the liquid phase comprises at least one sclerosing agent and is
at least 20% vol/vol of at least one viscosity enhancing agent; and
the gas phase comprises at least 50% CO₂;
and wherein the foam has a density less than 0.25 g/ml and half life of
greater than 100 secs.
- 10 2. A foam of claim 1, wherein the gas phase comprises at least
75% CO₂.
3. A foam of claim 1, wherein the gas phase comprises at least
90% CO₂.
- 15 4. A foam of claim 1, wherein the gas phase comprises at least
99% CO₂.
5. A foam of claim 1, wherein the gas phase consists essentially of
CO₂.
6. A foam of claim 1, wherein the half life is at least 120 seconds
7. A foam of claim 1, wherein the half life is at least 150 seconds.
- 20 8. A foam of claim 1, wherein the half life is at least 180 seconds.
9. A foam of claim 1, wherein the density ranges from 0.07 to 0.22
g/ml.
10. A foam of claim 1, wherein the density ranges from 0.07 to 0.19
g/ml.
- 25 11. A foam of claim 1, wherein the density ranges from 0.07 to 0.16
g/ml.
12. A foam of claim 1, wherein the density ranges from 0.08 to 0.14
g/ml.
13. A foam of claim 1, wherein the gas phase further comprises
30 another physiologically acceptable gas that is dispersible in blood.
14. A foam of claim 1, wherein the gas phase further comprises O₂.

15. A foam of claim 1, wherein the gas phase consists essentially of CO₂ and O₂.
16. A foam of claim 1, wherein the at least one viscosity enhancing agent is chosen from glycerol and PVP.
- 5 17. A foam of claim 1, wherein the at least one viscosity enhancing agent is chosen from glycerol.
18. A foam of claim 1, wherein the at least one sclerosing agent is chosen from polidocanol, glycerol and sodium tetradecyl sulphate.
- 10 19. A foam of claim 1, wherein the at least one sclerosing agent is polidocanol.
20. A foam of claim 1, wherein the polidocanol is present in a concentration ranging from 0.5 to 4% vol/vol in the liquid phase.
21. A foam of claim 1, wherein the liquid phase further comprises water and/or saline solution.
- 15 22. A foam of claim 1, wherein the liquid phase further comprises alcohol.
23. A foam of claim 1, wherein the saline solution is phosphate buffered saline with a pH ranging from 6.0 to 8.0.
24. A foam of claim 1, wherein the foam is capable of being passed
20 down a 21 gauge needle such that 50% or more by number of its gas bubbles

of at least 25 μ m remain at 150 μ m diameter or less and at least 95% of these bubbles at 280 μ m diameter or less.

25. A foam of claim 1, wherein at least 50% by number of the gas bubbles of at least 25 μ m diameter are of no more than 120 μ m diameter and
5 at least 95% of these gas bubbles are of no more than 250 μ m.

26. A method for angiologic treatment comprising injecting a foam of claim 1 into vessels to be treated.

27. A method for phlebologic treatment comprising injecting a foam of claim 1 into vessels to be treated.

10 28. The method of claim 25 wherein substantially the entire greater saphenous vein of one leg of a human patient is treated by a single injection of foam.

29. The method of claim 27 wherein the single injection uses an amount ranging from 10ml to 50ml of foam.

15 30. The method of claim 27 wherein the single injection uses an amount ranging from 10ml and 40ml.

31. The method of claim 27 wherein the single injection uses an amount ranging from 15ml and 30ml.

32. A foam comprising a liquid phase and a gas phase wherein
20 the liquid phase comprises at least one sclerosing agent and is at least 20% vol/vol of at least one viscosity enhancing agent; and

the gas phase comprises at least 50% CO₂;
and wherein the foam has a density less than 0.25 g/cm a
viscosity ranging from 2.0 to 3.5 cP

- 5 33. A foam of claim 31, wherein the viscosity ranges from 2.0 to 3.0
 cP.
34. A foam of claim 31, wherein the gas phase comprises at least
75% CO₂.
35. A foam of claim 31, wherein the gas phase comprises at least
90% CO₂.
- 10 36. A foam of claim 31, wherein the gas phase comprises at least
99% CO₂.
37. A foam of claim 31, wherein the gas phase consists essentially
of CO₂.
38. A foam of claim 31, wherein the half life is at least 120 seconds
- 15 39. A foam of claim 31, wherein the half life is at least 150 seconds.
40. A foam of claim 31, wherein the half life is at least 180 seconds.
41. A foam of claim 31, wherein the density ranges from 0.07 to
0.22 g/ml.
42. A foam of claim 31, wherein the density ranges from 0.07 to
- 20 0.19 g/ml.
43. A foam of claim 31, wherein the density ranges from 0.07 to
0.16 g/ml.

44. A foam of claim 31, wherein the density ranges from 0.08 to 0.14 g/ml.
45. A foam of claim 31, wherein the gas phase further comprises another physiologically acceptable gas that is dispersible in blood.
- 5 46. A foam of claim 31, wherein the gas phase further comprises O₂.
47. A foam of claim 31, wherein the gas phase consists essentially of CO₂ and O₂.
48. A foam of claim 31, wherein the at least one viscosity enhancing
10 agent is chosen from glycerol and PVP.
49. A foam of claim 31, wherein the at least one viscosity enhancing agent is chosen from glycerol.
50. A foam of claim 31, wherein the at least one sclerosing agent is chosen from polidocanol, glycerol and sodium tetradecyl sulphate.
- 15 51. A foam of claim 31, wherein the at least one sclerosing agent is polidocanol.
52. A foam of claim 31, wherein the polidocanol is present in a concentration ranging from 0.5 to 4% vol/vol in the liquid phase.
53. A foam of claim 31, wherein the liquid phase further comprises
20 water and/or saline solution.

54. A foam of claim 31, wherein the liquid phase further comprises alcohol.

55. A foam of claim 31, wherein the saline solution is phosphate buffered saline with a pH ranging from 6.0 to 8.0.

5 56. A foam of claim 31, wherein the foam is capable of being passed down a 21 gauge needle such that 50% or more by number of its gas bubbles of at least 25 μ m remain at 150 μ m diameter or less and at least 95% of these bubbles at 280 μ m diameter or less.

57. A foam of claim 31, wherein at least 50% by number of the gas
10 bubbles of at least 25 μ m diameter are of no more than 120 μ m diameter and at least 95% of these gas bubbles are of no more than 250 μ m.

58. A method for angiologic treatment comprising injecting a foam of claim 31 into vessels to be treated.

59. A method for phlebologic treatment comprising injecting a foam
15 of claim 31 into vessels to be treated.

60. The method of claim 59 wherein substantially the entire greater saphenous vein of one leg of a human patient is treated by a single injection of foam.

61. The method of claim 59 wherein the single injection uses an
20 amount ranging from 10ml to 50ml of foam.

62. The method of claim 59 wherein the single injection uses an amount ranging from 10ml and 40ml.

63. The method of claim 59 wherein the single injection uses an amount ranging from 15ml and 30ml.

64. A method for producing a foam comprising
passing a mixture comprising at least one physiologically acceptable
5 blood dispersible gas and at least one aqueous sclerosant liquid through one or more passages having at least one cross-sectional dimension of from 0.1 to 15 μm ,

the ratio of gas to liquid being controlled such that the foam is produced having a density less than 0.25 g/cm³ and a half-life of greater than
10 100 secs.

65. The method of claim 64, wherein the physiologically acceptable blood dispersible gas is chosen from CO₂, O₂ and mixtures thereof.

66. The method of claim 64, wherein the physiologically acceptable blood dispersible gas is at least 50% CO₂.

15 67. The method of claim 64, wherein the physiologically acceptable blood dispersible gas comprises at least 75% CO₂.

68. The method of claim 64, wherein the physiologically acceptable blood dispersible gas comprises at least 90% CO₂.

69. The method of claim 64, wherein the physiologically acceptable
20 blood dispersible gas comprises at least 99% CO₂.

70. The method of claim 64, wherein the physiologically acceptable blood dispersible gas consists essentially of CO₂.

71. The method of claim 64, wherein the half life is at least 120 seconds
72. The method of claim 64, wherein the half life is at least 150 seconds.
- 5 73. The method of claim 64, wherein the half life is at least 180 seconds.
74. The method of claim 64, wherein the density ranges from 0.07 to 0.19 g/ml.
75. The method of claim 64, wherein the mixture further comprises
10 at least 20% vol/vol of at least one viscosity enhancing agent.
76. The method of claim 75, wherein the at least one viscosity enhancing agent is chosen from glycerol and PVP.
77. The method of claim 76, wherein the at least one viscosity enhancing agent is chosen from glycerol.
- 15 78. The method of claim 64, wherein the at least one sclerosing agent is chosen from polidocanol, glycerol and sodium tetradecyl sulphate.
79. The method of claim 78, wherein the at least one sclerosing agent is polidocanol.
80. The method of claim 64, wherein the foam has a viscosity
20 ranging from ranging from 2.0 to 3.5 cP.

81. The method of claim 64, wherein the foam is capable of being passed down a 21 gauge needle such that 50% or more by number of its gas bubbles of at least 25 μ m remain at 150 μ m diameter or less and at least 95% of these bubbles at 280 μ m diameter or less.

5 82. The method of claim 64, wherein at least 50% by number of the gas bubbles of at least 25 μ m diameter are of no more than 120 μ m diameter and at least 95% of these gas bubbles are of no more than 250 μ m.

83. A device for producing a foam comprising a housing comprising
a pressurisable chamber comprising a solution comprising at least one
10 sclerosing agent in a physiologically acceptable solvent;

a pathway with one or more outlet orifices by which the solution may pass from the pressurisable chamber to exterior of the device through said one or more outlet orifices and a mechanism by which the pathway from the pressurisable chamber to the exterior can be opened or closed such that,
15 when the pressurisable chamber is pressurized and the pathway is open, the solution will be forced along the pathway and through the one or more outlet orifices ;

said housing incorporating one or more of (a) a pressurized source of at least one physiologically acceptable gas that is dispersible in blood and (b)
20 an inlet for the admission of said gas; the gas being in contacted with the solution on activation of the mechanism such as to produce a gas/solution mixture; and

said pathway to the exterior of the housing including one or more elements defining one or more passages of cross sectional dimension ranging

from 0.1 μm to 15 μm , through which the solution and gas mixture is passed to reach the exterior of the device, said passing of said mixture through the passages forming a foam with a density ranging from 0.07 to 0.19 g/mL and a half-life of at least 100 seconds.

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84. The device of claim 84, wherein the cross sectional dimension is diameter.

85. A device for producing a foam comprising a housing comprising a pressurisable chamber, at least part filled or fillable with a solution comprising at least one sclerosing agent in a physiologically acceptable solvent and/or a physiologically acceptable blood dispersible gas; a pathway by which the contents of the chamber may be passed to exterior of the housing through one or more outlet orifices and a mechanism by which the chamber can be pressurized such that its contents pass to the exterior along the pathway and through one or more outlet orifices

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said pathway to the exterior of the housing or the chamber comprising one or more elements defining one or more passages of cross sectional dimension ranging from 0.1 μm to 15 μm through which the contents of the chamber may be passed, whereby on passing through the passages the solution and gas form a foam with a density ranging from 0.07 to 0.19 g/mL and having a half-life of at least 100 seconds.

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86. The device of claim 85, wherein the cross sectional dimension is diameter.

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